IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARIE DIFIORE, **Plaintiff,** **v.** **CSL BEHRING, U.S., LLC,** **and** **CSL BEHRING, LLC,** **Defendants.**	**CIVIL ACTION NO. _____** **JURY TRIAL DEMANDED**

COMPLAINT & JURY DEMAND

Plaintiff Marie DiFiore, by and through her undersigned attorneys, Bell & Bell LLP, hereby files the following Complaint and Jury Demand ("Complaint").

PRELIMINARY STATEMENT

1. This is an action for an award of damages, attorneys' fees, and other relief on behalf of Plaintiff Marie DiFiore, a former employee of CSL Behring U.S., LLC and CSL Behring LLC (collectively "CSL" or "Defendants"). Ms. DiFiore has been harmed by the retaliation she was subjected to as a result of her opposition to and refusal to engage in unethical and illegal conduct with respect to the marketing and promotion of CSL's pharmaceutical products, her efforts in furtherance of the False Claims Act, her efforts to prevent one or more violations of the False Claims Act, and her opposition to and refusal to engage in other unethical and illegal conduct. This action arises under the anti-retaliation provisions of the False Claims Act, 31 USC 3730(h) and the common law of Pennsylvania.

JURISDICTIONAL STATEMENT

2. This Court has original jurisdiction over all civil actions arising under the Constitution, laws, or treaties of the United States pursuant to 28 U.S.C. §§ 1331 and 1391.

3. This Court has supplemental jurisdiction over any Pennsylvania state law claims pursuant to 28 U.S.C. § 1367.

VENUE

4. This action properly lies in the Eastern District of Pennsylvania, pursuant to 28 U.S.C. § 1391(b) because the claim arose in this judicial district.

5. Venue in the Eastern District of Pennsylvania is also authorized pursuant to 31 U.S.C. § 3730(h)(2).

PARTIES

6. Plaintiff Marie DiFiore is an individual who resides at 2062 Silverwood Drive, Newtown, Pennsylvania 18940.

7. Defendant CSL Behring U.S., LLC is a business entity organized and existing under state law with a place of business at 1020 First Avenue, King of Prussia, Pennsylvania 19406 that employed Plaintiff.

8. Defendant CSL Behring LLC is a business entity organized and existing under state law with a place of business at 1020 First Avenue, King of Prussia, Pennsylvania 19406 that employed Plaintiff.

9. At all relevant times, CSL has been a "person" and/or "employer" within the meaning of the False Claims Act and/or the Pennsylvania common law.

10. At all relevant times, Ms. DiFiore has been an "employee" within the meaning of

the False Claims Act and/or the Pennsylvania common law.

FACTS

11. CSL is a pharmaceutical company that produces and markets plasma protein biotherapeutics.

12. Ms. DiFiore was hired by CSL in 2008, and was initially retained as an Associate Director of Marketing.

13. Ms. DiFiore's performance with CSL was exemplary, and until the events that are the subject of this Complaint, Ms. DiFiore received consistently excellent performance reviews.

14. Ms. DiFiore's work at CSL was consistently praised; she achieved two President award nominations, was acknowledged as a top performer in marketing, and was promoted to a Director level position at CSL as a result of her strong performance.

15. Ms. DiFiore's most recent salary with CSL was $180,000, and her compensation package also included a 20 percent annual bonus, and 650 shares of CSL stock each year.

16. Ms. DiFiore's duties as Associate Director of Marketing, and later, after a promotion, as Director of Marketing, included leading the commercialization and launch of 3 new CSL pharmaceutical products: RiaSTAP, Beriplex and Corifact. In addition, in 2010, Ms. DiFiore was given the additional responsibility of managing marketing for Albumin.

17. Shortly after Ms. DiFiore began working at CSL, she began to observe a culture of resistance to legal compliance and a willingness to bend rules with respect to

product marketing and medical education.

18. Ms. DiFiore's position included responsibilities relating to the marketing of RiaSTAP.

19. RiaSTAP was approved by the FDA in 2009 for a limited indication, to treat congenital (chronic) coagulation deficiencies, and the projected annual revenues related to this narrow indication were less than $2 million.

20. CSL planned from the outset to widen RiaSTAP sales through off-label promotion and CSL has used various means to encourage the use of RiaSTAP for an unapproved use, treatment of acute bleeding situations or acquired bleeding (e.g. trauma and surgery related use), for which potential revenue is $100-$300 million per year.

21. CSL's intention to promote RiaSTAP off-label was evident from internal marketing documents.

22. For example, prior to the FDA's approval of RiaSTAP, Senior Director of Marketing Janice Cannizzo insisted that Ms. DiFiore use a global template for a marketing presentation for RiaSTAP, despite Ms. DiFiore's objection to the fact that the template included market share penetration for procedures outside of RiaSTAP's proposed indication, and that revenue for such off-label uses was considered by CSL in evaluating return on investment.

23. CSL management also directed that Ms. DiFiore include off-label sales in strategic forecast/manufacturing reports for RiaSTAP.

24. Although the then-current indication for RiaSTAP would likely result in only approximately $1.5 million in annual sales, even early forecasts limited to cardiac

usage only projected sales of up to $100 million. Subsequent forecasts, which included both cardiac and other usages, projected sales of up to $300 million.

25. Ms. DiFiore requested that she be absolved from forecasting duties, but the request was denied and Ms. DiFiore's forecasts were often overridden by senior management to raise RiaSTAP forecasted sales numbers to levels that could only be realized through off-label sales.

26. Beginning in mid to late 2011, following the promotion of Ingolf Sieper to a position leading Global Commercial Operations, Ms. DiFiore observed an increased willingness by CSL management to engage in unethical and illegal practices.

27. Dr. Sieper was specifically promoted to grow the acquired bleeding franchise and was well versed in tactics used to grow RiaSTAP sales in countries with and without the acquired bleeding indication.

28. Shortly after Dr. Sieper was promoted, it became clear to Ms. DiFiore that CSL was becoming very aggressive in its questionable practices.

29. Following Dr. Sieper's appointment, requests to implement medical education programs on acquired bleeding increased and CSL insistently promoted RiaSTAP for acquired bleeding, an unapproved use, under the auspices of medical education.

30. Ms. DiFiore opposed this practice, and the lack of appropriate separation between marketing and medical education, but her concerns were not addressed.

31. Ms. DiFiore was forced to repeatedly decline suggestions that she implement European medical education techniques and programs in the United States to

improve RiaSTAP sales, despite the fact that RiaSTAP lacked the acquired bleeding indication in the United States.

32. For example, during a meeting in November 2011, there were presentations demonstrating that the off-label activities in other countries had a positive impact on revenue.

33. CSL Global Lead Jan Hoesche asked Ms. DiFiore if such techniques could be implemented in the United States, and Ms. DiFiore again informed CSL management that such activities would violate FDA regulations.

34. CSL management repeatedly made clear to Ms. DiFiore that she was expected to support CSL's marketing of RiaSTAP for acquired bleeding, despite the lack of an approved indication for that use.

35. For example, during the Summer of 2011, Ms. DiFiore was specifically told by Ms. Cannizzo that she needed to be "more flexible" with regard to RiaSTAP programs.

36. When Ms. DiFiore reiterated that she believed that CSL was already being too aggressive with respect to marketing RiaSTAP for acquired bleeding, Ms. Cannizzo and other members of senior management ignored her concerns and again directed her to be "more flexible."

37. Ms. DiFiore also opposed CSL's off-label promotion of RiaSTAP through its efforts to partner with Rotem, a manufacturer of surgery instruments, in the promotion of RiaSTAP.

38. CSL worked with Rotem with the intention that when a Rotem instrument revealed a particular deficiency, Rotem sales personnel would suggest the use of

RiaSTAP to address the deficiency.

39. This collaboration included having CSL personnel present on Rotem sales calls, sharing business plans with Rotem, and sponsoring Rotem lectures.

40. Dr. Sieper personally emphasized to Ms. DiFiore the importance of Rotem to CSL's RiaSTAP marketing strategy.

41. For example, Dr. Sieper told Ms. DiFiore that she should become "an expert in the Rotem technology."

42. Senior Vice President Lynne Powell, acting on a directive from Dr. Sieper, took several steps to strengthen the relationship between Rotem and CSL, holding an intensive training meeting with CSL's Medical Science Liaisons on Rotem, including organizing a meeting in January 2012 with Rotem.

43. When Ms. Cannizzo directed Ms. DiFiore to attend this meeting, Ms. DiFiore protested on the basis that the Rotem/CSL relationship encouraged off-label promotion with which she should not be involved.

44. In response, Ms. Cannizzo criticized Ms. DiFiore and clearly tied her resistance to off-label activities to her performance, stating that as a Director, Ms. DiFiore needed to "demonstrate leadership and flexibility."

45. CSL also sought to expand its inappropriate collaborations with surgery instrument vendors beyond Rotem, and Ms. DiFiore was invited to a meeting with Haemonetics to discuss such a collaboration.

46. When Ms. DiFiore expressed concerns about the propriety of the Haemonetics meeting she was disinvited from the meeting. Ms. DiFiore maintains that this was a result of her criticisms of CSL's practices with Rotem, as well as the fact that

she had been labeled a "whistleblower" following the company's internal audit.

47. Ms. DiFiore received several complaints from Medical Science Liaisons, who also raised concerns regarding the propriety of CSL's directions to them in marketing RiaSTAP.

48. When Ms. DiFiore communicated these concerns to CSL management, she again faced opposition and disapproval from management.

49. During her employment with CSL, Ms. DiFiore repeatedly and specifically warned her supervisors and colleagues that the practices in question relating to RiaSTAP were exposing CSL to potential exposure for liability for fraud relating to off-label marketing, including a potential government investigation or action relating to fraudulent and off-label marketing.

50. On several occasions when discussing forecasting and other off-label marketing concerns stemming from senior management requests, Ms. Cannizzo again commented that Ms. DiFiore needed to "demonstrate flexibility" and commented that Ms. DiFiore's perspective was often "too black and white." Ms. Cannizzo commented that Ms. DiFiore needed to "understand shades of gray." Ms DiFiore's response was that "black and white is what keeps you out of trouble. Gray is what sends you to jail." Ms. Cannizzo was clearly not happy with Ms. DiFiore's response.

51. Ms. DiFiore also expressed her opposition to CSL's practices in the Fall of 2011, when the Global Team circulated an email regarding a fine of $25 million received by Novo Nordisk for off-label promotion.

52. In connection with this email, Hanno Waldhauser commented on the fine with an

indication that the fine was worthwhile, stating that Novo Nordisk likely made "at least 10-fold the fine" from off-label promotion.

53. During this email exchange, Ms. DiFiore stated her unequivocal disapproval for emulating Novo's strategy, stating "Novo is not the model we should use to assess what type of label we get. I need to get a broad label that allows us to promote on-label to maximize the revenue for RiaSTAP in the US. This is the only approach I can support."

54. Ms. DiFiore's duties as Associate Director of Marketing and later as Director of Marketing also included leading the launch of CSL's drug, Beriplex.

55. Beriplex reverses the effect of Warfarin, a type of anti-coagulant, and is used in cases of significant bleeding in patients with a coagulopathy.

56. CSL's inappropriate promotional practices also extended to Beriplex.

57. For example, prior to Beriplex's approval by the FDA, CSL seeded the market for off-label use of Beriplex with new and recently launched non-warfarin oral anticoagulants, despite the fact that Beriplex was only approved for use with warfarin oral anticoagulants, through clinical studies, publication planning and medical education initiatives. Again, Ms. DiFiore refused to participate or engage in this activity.

58. During the time period when the FDA was considering approval of Beriplex, Ms. DiFiore attended a Core Project Team Meeting (CPT) update in December 2011 relating to Beriplex where CSL management blatantly expressed their willingness to violate FDA regulations depending on the potential profit or loss associated with compliance.

59. Specifically, during the meeting senior management made a decision to delay openly reporting two adverse events associated with the Beriplex phase III clinical trial because of the potential delay that timely reporting might cause.

60. This decision is reflected in a follow-up power point presentation document dated February 29, 2012 entitled "Beriplex BLA Submission and Millings SAEs."

61. Although CSL later relented to pressure to reverse this decision, the power point presentation documented CSL's decision to delay reporting adverse events to the FDA because appropriate reporting would cause a two month delay for the program, and to instead include the additional adverse events in a safety update as a "late finding."

62. The power point presentation included an express acknowledgement of a calculated decision to "take the risk" in order to avoid a delay in the program, specifically, "On 1 Dec 2012 [sic] PSG decided to take the risk and to submit the updated CSR with the 10 weeks safety update."

63. In December 2011, after repeated complaints by Ms. DiFiore (and others), CSL initiated an audit process.

64. Following this audit, Ms. DiFiore was labeled as a "whistleblower" and was shut out of meetings relating to the audit, and not advised of the results of the audit.

65. After the audit, during which Ms. DiFiore shared certain concerns with auditors, efforts to retaliate against Ms. DiFiore increased significantly.

66. Ms. DiFiore had numerous conversations with CSL's legal and compliance departments regarding her concerns, with no resolution.

67. In addition to the unethical and illegal conduct Ms. DiFiore opposed and refused

to engage in relating to off-label promotion and other activities that would violate the False Claims Act, Ms. DiFiore also opposed other illegal activity at CSL.

68. In late 2011, Ms. DiFiore reviewed a draft Research and Development presentation, which CSL intended to present to potential investors.

69. Ms. DiFiore became concerned about several misleading and inappropriate items included in this Research and Development report.

70. For example, the report highlighted a Hanover Clinical Trial, relating to RiaSTAP, even though the clinical trial had not been published in a peer review journal, and had in fact been rejected by several journals because the quality of the study had been called into question.

71. The research and development report also included misleading information regarding the potential approval timelines for certain indications of RiaSTAP, despite the fact that CSL had not taken the necessary steps to conduct and advance the trials necessary for all such indications.

72. When Ms. DiFiore raised complaints regarding these and other problems with the presentation, and her concern that the presentation was misleading to potential investors, Ms. Cannizzo told her that it was not appropriate for the marketing department to comment on research and development investor presentations.

73. Ms. DiFiore also believed that CSL sought to mislead investors and potential investors through its decision to delay the reporting of adverse events relating to Beriplex, described above, and through its conduct relating to the Plasma Protein Therapeutics Association described below.

74. In 2011, during the pendency of several anti-trust lawsuits alleging that CSL conspired with other companies to restrict the output of blood plasma to artificially control the process of plasma derived protein therapies, Ms. DiFiore attended an industry conference in Brussels as the United States CSL Plasma Protein Therapeutics Association ("PPTA") representative.

75. During a dinner held at the conference, Albert Farragia, the Vice President of PPTA, stated to Director of Commercial Development/Critical Care George Henckle, "I need to talk to you, but before I do, I need to clarify that now I am talking to you as a friend, not as head of PPTA…"

76. Ms. DiFiore excused herself to the ladies room in order to avoid the conversation, but as she was leaving heard Mr. Farragia begin to disclose information regarding Baxter's manufacturing process to Mr. Henckle.

77. Ms. DiFiore was forced to excuse herself several times during this dinner and when she later told Ms. Cannizzo about her discomfort with the unethical and illegal conduct she observed, Ms. Cannizzo commented that Ms. DiFiore had done "the right thing" by excusing herself and indicated that she would discuss the situation with John Neff of CSL's legal department. However, to Ms. DiFiore's knowledge, Ms. Cannizzo did not raise the issue with Mr. Neff, and no action was taken to address her concerns.

78. Ms. DiFiore complained to many individuals at CSL regarding her concerns relating to off-label marketing and other illegal and unethical activity, including former President Robert Lefebvre, as well as to John Neff and Susan Morris of the legal department.

79. In late 2011, after Ms. DiFiore began to consistently raise her compliance and other concerns in writing, she became the target of concerted efforts to criticize her performance and marginalize her at CSL.

80. Soon thereafter, management began to claim that Ms. DiFiore's performance was lacking, and created reasons to pressure Ms. DiFiore to leave her position.

81. Beginning in December 2011, and continuing until her constructive termination in May 2012, Ms. DiFiore was vilified and criticized constantly, despite the fact that just 8 weeks prior she had been promoted to the position of full Director, and despite the fact that she had a strong record of 4 years of exemplary performance.

82. Between December 2011 and May 2012, Ms. Cannizzo began closely monitoring Ms. DiFiore's activities and criticizing nearly every action that Ms. DiFiore took, berating Ms. DiFiore at every opportunity and creating unjustified written criticisms of Ms. DiFiore's work.

83. In January 2012, Ms. DiFiore was given a warning letter accusing her of being "aggressive," "disrespectful" and not "collaborative" during a meeting.

84. The January 2012 warning letter was given to Ms. DiFiore after she complained about inappropriate conduct by Allan Alexander, Director, MTAL, Acquired Bleeding.

85. Mr. Alexander regularly engaged in aggressive behavior and used profanity during meetings, consistently missed deadlines, and had several other complaints lodged against him with Human Resources.

86. CSL retained a coach to assist Ms. DiFiore, Alan Alexander and the Beriplex team, but rather than provide Ms. DiFiore with a list of potential coaches and

allowing Ms. DiFiore to select from that list, CSL chose the coach without Ms. DiFiore's input. At times the coach's efforts were blocked as a result of interference and lack of support from Ms. Cannizzo.

87. The January 2012 warning letter to Ms. DiFiore was filled with inaccuracies regarding the alleged incident.

88. The warning letter contained language used to describe Ms. DiFiore's allegedly inappropriate behavior, which merely reflected ongoing frustration with Ms. DiFiore's insistence on raising concerns regarding illegal and unethical conduct.

89. This unjustified warning letter then served as the basis for Ms. DiFiore being rated as "needs improvement" under two objectives in her mid-year performance review.

90. Ms. DiFiore immediately identified the real motivation for these criticisms and noted in her February 1, 2012 response to her mid-year review, "I am gravely concerned that my complaint to HR regarding Allan and honest feedback to auditors regarding my concerns over non-compliant RiaSTAP medication education activities is contributing to the recent negative perception of my performance."

91. In further retaliation for her complaints, CSL management changed Ms. DiFiore's performance objectives mid-year, and then placed Ms. DiFiore on a performance improvement plan in May 2012.

92. The performance improvement plan was prepared in a manner that was clearly meant to harass Ms. DiFiore and set her up to fail, for example, by including goals that were clearly not achievable within the 45-day period of the plan.

93. The performance improvement plan also included clearly erroneous information regarding Ms. DiFiore's alleged performed deficiencies.

94. For example, in the plan document Ms. DiFiore was accused of giving inaccurate information regarding the work of another colleague to Dr. Sieper, however, Ms. DiFiore has documentation showing that her statement to Dr. Sieper was correct.

95. The performance improvement plan also included criticisms of Ms. DiFiore's "lack of political savvy," which is another reference to CSL's dissatisfaction with Ms. DiFiore's refusal to participate in unethical and illegal activities.

96. When Ms. DiFiore complained to Human Resources that the Performance Improvement Plan was obviously designed to push her out of the company, and did not allow any real opportunity for her to succeed on the plan, Director of Human Resources Trina Hendri essentially acknowledged that this was the case, and did not deny the accuracy of Ms. DiFiore's conclusions. During this meeting, Ms. DiFiore explicitly told Ms. Hendri that her situation with CSL was the result of her complaints regarding off-label marketing and proposed discussions with CSL to attempt to resolve the situation.

97. Moreover, following the Performance Improvement Plan, and Ms. DiFiore contacting Ms. Hendri regarding the Performance Improvement Plan and related issues, Ms. Cannizzo became even more hostile toward Ms. DiFiore.

98. The harassment and concerted efforts to remove Ms. DiFiore from her position created a hostile and abusive work environment that was intolerable to Ms. DiFiore, as it would have been to any reasonable employee.

99. Ms. DiFiore attempted repeatedly to find an amicable solution to her situation

with CSL, without success. For example, Ms. DiFiore asked whether there might be another position available for her, but despite her extensive experience was told there were no available positions. However, shortly thereafter, CSL retained a marketing consultant, Miriam Hayes, who performed duties that Ms. DiFiore was well qualified to perform.

100. CSL's actions had a significant detrimental impact on Ms. DiFiore, including negative effects to her health, leaving Ms. DiFiore with no choice but to end her employment with CSL. For example, shortly before her separation from CSL, Ms. DiFiore was forced to go to a hospital emergency room to address a stress related condition.

101. Any reasonable employee in Ms. DiFiore's position would have been left with no other choice than to resign.

102. CSL's actions described herein amount to a constructive termination of Ms. DiFiore's employment with CSL.

103. As a result of her constructive termination, Ms. DiFiore has suffered and continues to suffer lost wages and financial damages, including lost salary, lost CSL shares, and loss of bonus.

104. Additionally, at the time of her constructive termination Ms. DiFiore suffered the loss of unvested CSL shares worth approximately $80,000, and loss of her annual bonus of $36,000, that was imminently due to be paid.

105. CSL's actions have also caused Ms. DiFiore significant mental anguish, and have damaged her professional reputation.

COUNT I - RETALIATION IN VIOLATION OF THE FALSE CLAIMS ACT
(The False Claims Act, 31 U.S.C. § 3730(h))
Plaintiff v. All Defendants

106. Plaintiff repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

107. CSL harassed Ms. DiFiore and constructively terminated Ms. DiFiore in retaliation for Ms. DiFiore's lawful acts in furtherance of the goals of The False Claims Act, and in retaliation for Ms. DiFiore's efforts to stop one or more violations of the False Claims Act.

108. In retaliating against Ms. DiFiore for her lawful acts in furtherance of the goals of The False Claims Act, and her efforts to stop one or more violations of the False Claims Act, Defendants violated The False Claims Act, 31 U.S.C. § 3730(h).

109. As a result of Defendants' violation of The False Claims Act, Ms. DiFiore has suffered lost wages, including lost salary, lost CSL shares, and loss of bonus.

COUNT II – WRONGFUL TERMINATION
Plaintiff v. All Defendants

110. Plaintiff repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

111. CSL constructively terminated Ms. DiFiore as a result of Ms. DiFiore's opposition to and refusal to engage in unethical and illegal activity.

112. CSL constructively terminated Ms. DiFiore in violation of Pennsylvania public policy for her refusal to engage in unethical and illegal activity.

113. CSL constructively terminated Ms. DiFiore in violation of Pennsylvania public policy for her opposition to and refusal to participate in off-label promotions.

114. CSL constructively terminated Ms. DiFiore in violation of Pennsylvania public policy for her refusal to participate in creating false claims in the Commonwealth of Pennsylvania.

115. CSL constructively terminated Ms. DiFiore as a result of Ms. DiFiore's opposition to and refusal to engage in other illegal and unethical activity, including activities relating to disclosures made to investors and potential investors and activities relating to antitrust restrictions.

116. The above described conduct of CSL constituted wrongful termination of Plaintiff.

117. As a result of her wrongful termination, Ms. DiFiore has suffered lost wages, including lost salary, lost CSL shares, and loss of bonus.

PRAYER FOR RELIEF

118. Plaintiff repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

WHEREFORE, Plaintiff, Marie DiFiore, demands that judgment be entered in her favor and against Defendants:

a. Ordering reinstatement, or appropriate front pay;

b. Awarding compensatory damages to Plaintiff Marie DiFiore to make Plaintiff whole for all past and future lost earnings, benefits and earnings capacity which Plaintiff has suffered and will continue to suffer as a result of Defendants' conduct;

c. Awarding compensatory damages to Plaintiff Marie DiFiore for past and future emotional upset, mental anguish, loss of reputation, humiliation, loss of life's pleasures and pain and suffering;

d. Awarding punitive damages to Plaintiff Marie DiFiore;

e. Awarding Plaintiff double back pay damages, as appropriate, pursuant to the False Claims Act;

f. Awarding Plaintiff Marie DiFiore costs of this action together with her reasonable attorneys' fees;

g. Awarding Plaintiff Marie DiFiore such other damages as are appropriate under The False Claims Act, the common law of Pennsylvania, and any other applicable laws; and

h. Granting such other and further relief as this Court deems just and proper.

JURY DEMAND

119. Plaintiff hereby demands trial by jury as to all issues so triable.

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DATE: August 1, 2013